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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,958	11/13/2003	Eran Blaugrund	67705/JPW/GJG/JBC	9422

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EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
08/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,958	BLAUGRUND ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/28/07;5/31/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed June 28, 2007 have been received and entered into the application.

Action Summary

The rejection of claims 1-12 under 35 U.S.C. 103(a) as being unpatentable over Youdim et al. (WO 95/11016) in view of Kaal et al. (Journal of Neurochemistry, 2000) is hereby expressly withdrawn in view of newly founded art (Orru et al. 1999).

Upon further consideration of the newly found art, the rejection made in the previous Office Action is reformulated. Therefore, this Office Action is made non-final.

Specification

The specification is objected to because of the following informalities: it appears that the term "sustantially" on page 10, line 4, should be "substantially".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially" typographically recites as "sustantially" is vague and indefinite because it is not clear just how much or how less time period would qualify as "substantially concurrent".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youdim et al. (WO 95/11016) of record in view of Orru et al. (1999) and further in view of Kaal et al. (Journal of Neurochemistry, 2000) of record.

Youdim et al. teach Applicant's active agent, R(+)-N-propargyl-1-aminoindan (Rasagiline) useful for the treatment of a subject afflicted with Parkinson's disease and a neurodegenerative disease. (abstract). Youdim et al. teach the therapeutically effective amount of the agent is about 0.1mg to about 100mg. (page 23, lines 27-32, claim 29). These amounts encompass Applicant's amounts set forth in claims 4 and 12. Youdim et al. teach that a pharmaceutically acceptable salts of the agent include, but are not limited to, the mesylate, maleate, fumarate, tartrate, acetate, phosphate and sulfate salts. (page 21, line 34-page 22, line 4). Youdim et al. teach that Rasagiline is a

selective irreversible inhibitor of the B-form of monoamine oxidase enzyme (MAO-B). (page 1, lines 15-29).

Youdim et al. do not teach the treatment of amyotrophic lateral sclerosis (ALS) and further comprising 2-amino-6-trifluoromethoxy benzothiazole (riluzole) and its amounts.

Orru et al. teach that MAO-B hyperactivity account of the dopaminergic deficiency demonstrated in ALS like in Parkinson's disease (PD). Orru et al. teach that the formation of neurotoxic metabolites arising from the oxidative deamination catalyzed by MAO-B may be one of the causes for ALS as it is suggested in PD. (page 595 right-hand column lines 30-33).

Kaal et al. teach that riluzole is a drug currently used for the treatment of amyotrophic lateral sclerosis. Kaal et al. teach that ALS is a neurodegenerative disease characterized by selective motor neuron death. (abstract).

It would have been obvious to one of ordinary skill in the art to employ Rasagiline for the treatment of ALS because Youdim et al. teach that Rasagiline is useful for the treatment of a neurodegenerative disease and Parkinson's disease by inhibition of MAO-B enzyme and because MAO-B enzyme hyperactivity exhibits dopaminergic deficiency in ALS as taught by Orru et al. One of ordinary skill in the art would have been motivated to administer Rasagiline to ALS patients having MAO-B hyperactivity order to achieve an expected reduction of hyperactivity of MAO-B enzyme that exhibit symptoms of dopaminergic deficiency in ALS as taught by Orru et al. There is a reasonable expectation of successfully treating a dopaminergic deficiency in ALS in

patients by administration of Rasagiline because Orru et al. teach that hyperactivity of MAO-B enzyme exhibits dopaminergic deficiency in ALS and because Rasagiline is an irreversible MAO-B inhibitor that reduces MAO-B enzyme production as taught by Youdim et al.

It would have been obvious to one of ordinary skill in the art to combine riluzole in its therapeutic amounts with Rasagiline for the treatment of ALS because each of the active agent, particularly riluzole is a drug currently used for the treatment of neurodegenerative disease such as ALS, and because Rasagiline is useful for treating symptoms of dopaminergic deficiency in ALS. One would have been motivated to combine riluzole and Rasagiline in a single formulation for the treatment of ALS in order to achieve an expected additive effect of treating a patient suffering from ALS. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicants' arguments filed June 28, 2007 have been fully considered but they are not persuasive. Applicants argue that the effects of Rasagiline on ALS and of the combination treatment on ALS, could not be predicted from the prior art. This is not found persuasive because on the contrary, the effects of Rasagiline on the patient in need of treating ALS can be predicted from the prior art because Orru et al. teach that MAO-B enzyme hyperactivity are responsible for dopaminergic deficiency in ALS patients and because Rasagiline is irreversible MAO-B enzyme inhibitor that inhibits production of such enzyme. Therefore, there is a reasonable expectation of successfully treating ALS in a patient exhibiting with dopaminergic deficient symptoms. Applicants argue that Youdim et al. do not include ALS in their list of neurodegenerative disease and that neurodegeneration is often the cause of the disability in many diseases not usually classified as degenerative. This is not found persuasive because Youdim et al. does not expressly teach the treatment of ALS in their list of neurodegenerative disuse, but Youdim et al. teaches the treatment of neurodegenerative disorders including Parkinson' disease by reducing MAO-B enzyme. Orru et al. teach that hyperactivity of the enzyme causes dopaminergic deficiency in ALS. Applicants argue that it is unreasonable to expect a Parkinson's disease treatment to also successfully treat ALS because there is evidence in the prior art that ALS cannot be treated by a common Parkinson's disease treatment (e.g. amantadine). This is not found persuasive because first of all, amantadine classified as antiviral agent and it not the active agent at issue. Second of all, on the other hand, there is a reasonable expectation of success by administration of Rasagiline in ALS patients who

demonstrates dopaminergic deficit symptoms because Orru et al. teach that MAO-B hyperactivity account for the demonstrated dopaminergic deficiency in ALS patients. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
August 18, 2007